DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 6 2001

Re: TNKase
Docket No.: 01E-0098

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,385,732, filed by Genetech, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for TNKase, the human biological product claimed by the patent.

The total length of the regulatory review period for TNKase is 1,990 days. Of this time, 1,741 days occurred during the testing phase and 249 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 23, 1994.

   The applicant claims February 22, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 23, 1994, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: September 28, 1999.

   FDA has verified the applicant's claim that the product license application (BLA) for TNKase (BLA 99-0903) was initially submitted on September 28, 1999.

3. The date the application was approved: June 2, 2000.

   FDA has verified the applicant's claim that BLA 99-0903 was approved on June 2, 2000.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Ginger R. Dreger
Knobbe, Martens, Olson, & Bear, L.L.P.
620 Newport Center Drive, 16th Floor
Newport Beach, CA 92660